REMARKS

Claims 1-3, 5, 6, 9-11, 19-21, 23, 24, 27-29 and 39 remain active in the application. Undersigned counsel thanks Examiner Bahar for the October 2, 2003 interview, which is summarized below.

Claims 37 – 39 are objected to under 37 CFR 1.75(c) as being in improper dependent form. As agreed at the interview, claims 37 and 38 have been cancelled because the compounds are not non-steroidal anti-inflammatory compounds (NSAIDS), and so are not within the scope of claim 1. However, claim 39 has been retained because the recited compounds are all NSAIDS.

Claims 1, 3-10, 12-19, 21-28 and 30-39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hewitt et al, Lozada and Sharpe et al.

As now presented, the claims are directed specifically to a method for treating graft v. host disease of the mouth, including specific steps adapted to treatment of this particular immune disease.

Hewitt et al. teaches the use of cyclosporine in ointment formulations, for site-specific immune suppression, optionally combined with hydrocortisone or other immunosuppressants. While graft v. host disease is mentioned (col. 1, line 13 – 18), it is in connection with the well-known effectiveness of cyclosporine for treating T-cell mediated immune processes, such as allograft rejection, graft-versus-host disease, and autoimmune disease when administered systemically. This information would not have suggested the effectiveness of an azathioprine swish, as claimed, for treatment of this specific kind of immune disorder.

Lozada discloses topical treatment of mucosal lesions with immunosuppressants. Lozada's method involves the use azathioprine to lower the effective dose of prednisone (synergy). This method is not topical , and while it is indicated for several kinds of mucosal diseases including chronic inflammatory mucocutaneous disease (CIMD), lichen planus (LP), and others), graft v. host disease, which involves mouth lesions caused by tissue transplants away from the mouth, is not mentioned.

Sharpe et al. teaches a topical method for treatment of mucosal lesions using N-acetyl cysteine as the main active ingredient, with azithioprine as a secondary compound for enhancing the effectiveness of N-acetyl cysteine. As in Lozada, the difficult problem of graft v. host disease is not discussed.

Nothing in Lozada or Sharpe et al. would have suggested to a person of ordinary skill in the art that is selecting liquid formulations of the claimed compounds would be particularly effective for treatment of graft v. host disease; thus, the present invention would not have been obvious within the meaning of 35 U.S.C. §103(a).

Respectfully submitted,

Gilberto M. Villacorta, PH.D.
Registration No. 34,038
Robert W. Hahl, PH.D.
Registration No. 33,893

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061

Dated: May 21, 2004